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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,982	01/14/2002	Tariq M Rana	13257-00018	4387

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/14/2003

/o

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,982	RANA ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *6,10-15 and 20-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Office Action

Status of the Claims

1. Applicants' election with traverse of Group I (claims 1-5, 7-9, and 16-19) in paper no. 9 is acknowledged. Applicants' traversal is based upon the premise that the claims define a single general inventive concept since there is a technical relationship involving at least one common or corresponding special technical feature.

As previously set forth in paper no. 8, the regulations governing the claiming of different inventions in one national application are set forth under 37 C.F.R. § 1.141, 1.475, and 1.499. Applicants were reminded that if **multiple products,** processes of manufacture, and/or **uses** are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto, will be considered as the main invention in the claims (refer to PCT Article 17(3)(a) and § 1.476(c)). The novelty of the instant invention appears to be directed towards a synthesized oligourea comprising the basic arginine-rich region of HIV Tat. Applicants were advised that if this invention was elected, a single method of use would be included for examination. However, the remaining group does not share a special technical feature with Group I as set forth below:

a. Group I, claim(s) 1-5, 7-9, and 16-19, drawn to a **synthesized oligourea** comprising the **basic arginine-rich region** of **HIV Tat** and methods of inhibiting Tat/Tar binding interactions employing said compound.

b. Group II, claim(s) 6, 10-15, and 20-26, drawn to a **synthesized oligourea** that has a **specific binding affinity** for **any given nucleic acid** and methods of inhibiting protein-nucleic acid binding interactions employing said compound.

As previously set forth, the inventions listed as Groups I and II do **not** relate to a single inventive concept under PCT Rule 13.1

because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: **each of the identified groups is directed toward a different chemical compound (e.g., HIV Tat-derived oligourea or nucleic acid-derived oligourea) with disparate chemical structures, activities, and functions.** Moreover, the claimed inventions fail to make a contribution over the prior art as set forth below. Accordingly, the inventions lack a special technical feature and the lack of unity requirement as set forth in the last Office action was proper **and is therefore made FINAL.** Claims 1-5, 7-9, and 16-19 are currently under examination whereas claims 6, 10-15, and 20-26 have been withdrawn from further consideration.

35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in —
>
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
>
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

(f) he did not himself invent the subject matter sought to be patented.

3. Claims 1-5, 7-9, and 16-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Rana *et al.* (2003). Rana and colleagues disclose the preparation of Tat-derived oligoureas and their utilization to inhibit Tat activities (e.g., see cols. 39, 40, and 48-52). Accordingly, this teaching meets all of the claimed limitations.

4. Claims 1-5, 7-9, and 16-19 are rejected under 35 U.S.C. § 102(f) because the applicant did not invent the claimed subject matter. As disclosed supra in paragraph three, Rana and colleagues teach the instantly claimed invention. This publication lists three authors, including two of the inventors of the instant application. However, the publication also includes a third individual who is not a listed inventor in the instant application. However, the examiner presumes that all individuals contributed equally, and are presumably joint inventors, absent evidence to the contrary. Applicants are reminded that it is incumbent upon the inventors named in the application, in response to an inquiry regarding the appropriate inventorship under subsection (f), or to rebut a rejection under 35 U.S.C. 102(a) or (e), to provide a satisfactory showing by way of affidavit under 37 C.F.R. §§ 1.131 or 1.132 that the inventorship of the application is correct in that the reference discloses subject matter invented by the applicant rather than derived from the author or patentee notwithstanding the authorship of the article or the inventorship of the patent. *Ex parte Kusko*, 215 U.S.P.Q. 972, 974 (Bd. Pat. App. Int. 1981). *In re Katz*, 215 U.S.P.Q. 14, 18 (C.C.P.A. 1982). *In re Costello*, 219 U.S.P.Q. 389, 390 -91 (Fed. Cir. 1983).

5. Claims 1, 5, and 16-19 are rejected under 35 U.S.C. § 102(a) as being anticipated by Tamilarasu *et al.* (1999). This teaching discloses the preparation of Tat-derived oligoureas (see attached structures) and meets all of the claimed limitations.

35 U.S.C. § 112, First Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 7-9, and 16-19 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The disclosure describes the preparation of Tat-derived oligoureas and their ability to inhibit HIV-1 Tat binding to the Tar element in a suitable *in vitro* binding assay. Appropriately drafted claim language directed toward *in vitro* binding methods would be acceptable. However, the full breadth of the claims encompasses *in vitro* and both *in vivo* and *ex vivo* clinical applications. However, the disclosure fails to support both *in vivo* and *ex vivo* applications at this point in time.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making

such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The claims are of considerable breadth and encompass *in vitro*, *in vivo*, and *ex vivo* applications. However, the disclosure fails to provide support for any other application other than simple in vitro inhibitory methods. As set forth below, the factors governing the successful inhibition of viral replication in the clinical setting are complicated and unpredictable. The disclosure fails to provide any support addressing these issues.

2) The disclosure fails to provide any working embodiments as they pertain to both in vivo and ex vivo inhibitory methods. The only examples provided are derived from simple *in vitro* binding assays. However, these assays are not generally reflective of the true milieu where such compounds will be required to operate.

3) The prior art teaches that the generation of successful HIV-1 antivirals is a difficult, complex, and often unpredictable process. Several factors have contributed to antiviral failure including short serum half-lives, poor bioavailabilities, rapid clearance rates, sequestration of the drug by serum proteins, drug resistance due to the quasispecies nature of HIV-1 infection, and the uneven distribution of the compound throughout the body (Gait *et al.*, 1995). The disclosure fails to address any of these concerns.

Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the

skilled artisan to practice the claimed invention.

Correspondence

8. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

9. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

31 October, 2003